

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

MYLAN PHARMACEUTICALS INC.,

Plaintiff,

V.

MERCK & CO., INC.,

Defendant.

Civil No. 1:05-CV-1416

JUDGE SYLVIA H. RAMBO

Jury Trial Demanded

MEMORANDUM

Before the court are Defendant Merck & Co, Inc.’s (“Merck”) Motion to Dismiss (Doc. 19) and Contingent Motion to Transfer Under 28 U.S.C. § 1404(a) (Doc. 22). The parties have briefed the issues and the matters are ripe for disposition. For the reasons that follow, the court will grant Defendant’s motion to dismiss because the court lacks subject matter jurisdiction. Accordingly, the court will deny Defendant’s contingent motion to transfer as moot.

I. Background

A. The Hatch-Waxman and Medicare Amendments

The Federal Food, Drug, and Cosmetic Act of 1938 (“FDDCA”), 21 U.S.C. §§ 1 et seq., governs the procedures for the approval of pioneer and generic drugs. The FFDCA’s statutory scheme for the approval of generic drugs was first modified by the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Amendments”), Pub. L. No. 98-417, 98 Stat. 1585 (1984). In 2003, Congress further modified the generic drug approval scheme when it enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

(“Medicare Amendments”), Pub. L. No. 108-173, 117 Stat. 2066 (2003)¹ to prevent abuses associated with the patent code’s declaratory judgment provisions.

Under the current statutory scheme, pioneer drug manufacturers must file a New Drug Application (“NDA”) with the Food and Drug Administration (“FDA”) to obtain approval to manufacture and market a drug. 21 U.S.C. §§ 355(a)-(b)(1). An NDA contains comprehensive information demonstrating the drug’s safety and efficacy. *See id.* NDA-holders are also required to notify the FDA of all patents that cover the new drug. 21 U.S.C. §§ 355(b)(1), (c)(2). The FDA then lists the patents in what is commonly referred to as the “Orange Book.”²

A manufacturer of a generic version of an approved drug may then submit an Abbreviated New Drug Application (“ANDA”) to the FDA, in which it may rely on the NDA’s safety and efficacy studies. 21 U.S.C. §§ 355(j)(1), (2)(A)(I). An ANDA must include information establishing that the generic drug is the bioequivalent of the approved pioneer drug. 21 U.S.C. § 355(j)(2)(A). An ANDA must also contain one of four certifications regarding any patents that are listed in the Orange Book for the pioneer drug:

(I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

¹ The Hatch-Waxman Act is codified at 35 U.S.C. § 271. The relevant portions of the FDCA, as modified by the Hatch-Waxman and Medicare Amendments, are codified at 21 U.S.C. § 355.

² The official name of the publication is “Approved Drug Products with Therapeutic Equivalence Evaluations.”

21 U.S.C. §§ 355(j)(2)(A)(vii)(I-IV). “These are commonly referred to as paragraph I, II, III, and IV certifications.” *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1328 (Fed. Cir. 2005).

When an ANDA filer wants to sell its generic drug product before a listed patent has expired, it must file a paragraph IV certification. When filing a paragraph IV certification, the ANDA filer must also notify the owner of any relevant patents and NDA holder and provide them with a “detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” 21 U.S.C. §§ 355(j)(2)(B)(i), (iv).

The filing of the ANDA triggers a forty-five-day period during which the ANDA applicant is barred from filing a declaratory judgment action. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent holder files an infringement action within that forty-five-day period, the FDA may not approve the ANDA for thirty months, unless the suit is resolved or the patent expires earlier. *Id.* If the patent holder does not file an infringement suit during the forty-five-day period, the FDA may approve the ANDA. *Id.*

As an incentive to encourage early ANDA applicants, the Hatch-Waxman amendments provide for a 180-day marketing exclusivity period for the first ANDA applicant to make a paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv). The Medicare Amendments, which apply to the instant case, made various changes with respect to the exclusivity period provisions, including “forfeiture provisions”

that identify the circumstances in which the 180-day exclusivity period can be forfeited.³ 21 U.S.C. § 355(j)(5)(D).

The exclusivity period ensures that the only generic drug on the market during that time is that of the first ANDA filer because the FDA may not approve a subsequent ANDA for the same drug during the exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity period is triggered by the first commercial marketing of the drug (by either the pioneer drug owner or the first ANDA filer.) *Id.* However, it can also be triggered earlier, on the date on which a court enters judgment that the patent is invalid or not infringed, 21 U.S.C. § 355(j)(5)(B)(iii). Thus, an action involving a subsequent ANDA filer can result in a judgment that triggers the exclusivity period. *See id.*

The Medicare Amendments also added civil action provisions which state that if neither the patent-holder or NDA-holder brings an infringement action during the forty-five day period following receipt of the paragraph IV certification, the ANDA applicant may “bring a civil action . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval,” in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act). 21 U.S.C. § 355(j)(5)(C)(i).

³ The Medicare Amendments were enacted on December 8, 2003; the forfeiture provisions are applicable to ANDAs “filed after December 8, 2003, for which no paragraph IV certification was made before December 8, 2003.” *Teva*, 395 F.3d at 1329; Medicare Prescription Drug, Improvement and Modernization Act of 2003, § 1102(b). Mylan Pharmaceuticals, Inc. notified Merck about its ANDA and paragraph IV certification by letter dated April 26, 2005.

B. Factual Background

Merck developed a formulation of finasteride, which it markets under the brand name PROSCAR®,⁴ a drug used to treat symptomatic benign prostatic hyperplasia (enlarged prostate, known as “BPH”). Merck holds NDA No. 20-180, which the FDA approved, allowing Merck to market and sell the PROSCAR® finasteride formulation. Merck also holds several patents that relate to its finasteride product, including United States Patent Nos.: 1) 4,760,071 (“the ‘071 patent”), issued on July 26, 1988, which covers the compound itself; 2) 5,886,184 (“the ‘184 patent”), issued on May 23, 1999, which covers a particular crystalline form of finasteride; 3) 6,046,183 (“the ‘183 patent”), issued on April 4, 2000, which covers a method of treatment for BPH using finasteride in combination with another specific drug; and 4) 5,942,519 (“the ‘519 patent”), issued on August 25, 1999, which covers using finasteride specifically for patients who are suffering from precipitated acute urinary retention (“PAUR”). All four patents are listed in the FDA’s Orange Book for PROSCAR®.

On April 30, 2002, and July 2, 2003, Ivax Pharmaceuticals Inc., (“Ivax”) submitted ANDAs seeking to market generic forms of Merck’s PROSCAR® finasteride product. Ivax also notified Merck regarding its paragraph IV certifications for the ‘184 and ‘183 patents. Merck did not sue Ivax during the subsequent forty-five-day period and has not sued Ivax to date. Ivax was the first ANDA filer and is thus entitled to the benefit of the 180-day exclusivity period.

On April 26, 2005, Mylan notified Merck regarding Mylan’s ANDA for the same product, along with paragraph IV certifications for the ‘184 and ‘183

⁴ Mylan also markets finasteride under the brand name PROPECIA®.

patents. Mylan also submitted a section viii statement, pursuant to 21 U.S.C. § 355(j)(2)(A)(viii), stating that the '519 patent claims a method of using finasteride for which Mylan is not seeking approval. Merck did not sue Mylan during the subsequent forty-five-day period and has not sued Merck to date. The only communication that Mylan has received from Merck regarding its generic finasteride product is a letter dated June 9, 2005, indicating that Merck did not intend to sue within the forty-five-day period. Merck has declined to covenant not to sue Mylan for infringement of the patents.

To date, no company has filed a paragraph IV certification for the '071 patent, which expires on June 19, 2006. Both Ivax and Mylan have filed paragraph III certifications that they will wait until after the '071 expiration date to market their generic finasteride products. Merck has indicated that because finasteride is not covered *per se* by the '184, '183, or '519 patents, it is possible for a generic competitor to make and sell a generic finasteride product without infringing any of those patents.

C. Procedural History

Mylan Pharmaceuticals, Inc. ("Mylan") filed a Complaint on July 14, 2005, seeking a declaratory judgment that its generic finasteride drug product does not and will not infringe the '184, '183, and '519 patents. Merck filed a Motion to Dismiss (Doc. 19) on August 29, 2005, for lack of subject matter jurisdiction, claiming that no case or controversy exists. Because the court finds no case or

controversy, the court will grant Merck's Motion to Dismiss and dismiss the Complaint for lack of subject matter jurisdiction.⁵

II. Legal Standard

“ ‘A motion to dismiss under Rule 12(b)(1) challenges the jurisdiction of the court to address the merits of the plaintiff's complaint.’ ” *Vieth v. Pennsylvania*, 188 F. Supp. 2d 532, 537 (M.D. Pa. 2002) (quoting *Ballenger v. Applied Digital Solutions, Inc.*, 189 F. Supp. 2d 196, 199 (D. Del. 2002)). The motion should be granted where the asserted claim is “so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy.” *Coxson v. Pennsylvania*, 935 F. Supp. 624, 626 (W.D. Pa. 1996) (citing *Growth Horizons v. Delaware County*, 983 F.2d 1277, 1280-81 (3d Cir. 1993)).

A motion to dismiss under Rule 12(b)(1) may present either a facial or factual challenge to subject matter jurisdiction. *See Carpet Group Int'l v. Oriental Rug Imps. Ass'n*, 227 F.3d 62, 69 (3d Cir. 2000). This case presents a facial challenge because Defendant does not dispute, at this juncture, the jurisdictional facts alleged in the Complaint. *See* 2 James Wm. Moore et al., *Moore's Federal Practice* ¶ 12.30[4] (3d ed. 1999) (explaining the difference between a facial and factual challenge to subject matter jurisdiction pursuant to Rule 12(b)(1)). Therefore, the court must accept the facts alleged in the complaint as true and draw all reasonable

⁵ Merck also filed a Contingent Motion to Transfer Under 28 U.S.C. §1404(a). (Doc. 22.) The court will deny that motion as moot.

inferences in favor of the plaintiff. *Zinerman v. Burch*, 494 U.S. 113, 118 (1990); *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000).

III. Discussion

A. The Declaratory Judgment Act

The Declaratory Judgment Act provides in relevant part that “[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.” 28 U.S.C. § 2201(a). The Act’s actual controversy requirement parallels the federal jurisdictional requirement found in Article III of the Constitution. *Teva*, 395 F.3d at 1331.

Essentially, the court must determine “ ‘whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.’ ” *Id.* (quoting *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 810 (Fed. Cir. 1996)). If no actual controversy exists, then the court lacks jurisdiction to hear the case. *Id.* at 1332. However, even when the court determines that there is a controversy, it may exercise its discretion to decline jurisdiction. *Id.*

The inquiry regarding whether an actual controversy exists in a suit seeking a declaration of patent non-infringement or invalidity is two-fold. *Id.*

There must be both (1) an explicit threat or other action by the patentee [that] creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff [that] could constitute infringement, or

concrete steps taken with the intent to conduct such activity.

Id. In addition, with respect to the reasonable apprehension prong, “ ‘[w]hen the defendant’s conduct, including its statements falls short of an express charge, one must consider the totality of the circumstances in determining whether that conduct meets the first prong of the test.’ ” *Id.* (quoting *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988)).

Mylan and Merck agree that Mylan’s submission of the paragraph IV certification satisfies the second prong of the test. Accordingly, the issue before the court is whether any of Merck’s conduct established a reasonable apprehension that Merck would sue Mylan for infringement.

B. Analysis

Mylan acknowledges that Merck has not explicitly stated that it intends to sue Mylan for infringement of its finasteride patents (Def.’s Opp’n to Pl.’s Mot. to Dismiss at 12.) (“Merck has said nothing to Mylan or this Court about its intentions *after* the expiration of this 45-day period.”) Accordingly, the court will consider whether Merck’s conduct, under the totality of circumstances, establishes a reasonable apprehension that Merck will sue Mylan for infringement of the patents. *Teva*, 395 F.3d at 1332.

Mylan argues that the following Merck acts establish grounds for its reasonable apprehension of an infringement suit: 1) Merck’s listing of the finasteride patents in the Orange Book; 2) Merck’s prior history of defending its patents through litigation; 3) Merck’s public statements that it will defend its finasteride patents; and 4) Merck’s refusal to covenant not to sue Mylan for infringement. Mylan also argues that the Medicare Amendments civil suit provision (21 U.S.C. § 355(j)(5)(C))

provides a means to assert subject matter jurisdiction subject only to Article III requirements, which it believes to be different than the requirements of the two-prong test. Upon consideration of all of the circumstances, and in accordance with Federal Circuit precedent,⁶ the court finds that Mylan's arguments fail to establish a reasonable apprehension of suit.

1. Orange Book Listing

Mylan argues that Merck's listing of the patents in the Orange Book is sufficient on its own to establish a reasonable apprehension of suit because it represents Merck's position that it could reasonably assert an infringement suit with respect to its patents. *See* 21 U.S.C. § 355(b)(1) (providing that NDA applicants must file notice of any patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" – the FDA then lists these patents in the Orange Book). However, without more, Merck's compliance with the statutory listing requirement "should not be construed as a blanket threat to potential infringers" by patent owners. *Teva*, 395 F.3d at 1333. The Orange Book listing is insufficient to satisfy the objective intent to sue standard required to establish an actual controversy between a patentee and "any ANDA filer who submits a paragraph IV certification with respect to the patent." *Id.* Thus, Mylan's argument that Merck's Orange Book listing alone establishes a reasonable apprehension of suit fails.

⁶ Patent law appeals are heard by the Court of Appeals for the Federal Circuit; thus the law of the Federal Circuit applies. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 n.4 (Fed. Cir. 1992).

2. History of Litigation

Mylan argues that Merck's history of asserting its patents, including its finasteride patents, as well as other patents, through litigation involving other companies establishes a reasonable apprehension of suit here. Mylan relies on Merck's litigation against Dr. Reddy's specifically and Merck's litigation history generally. As a threshold matter, Merck's infringement litigation history is relevant but not dispositive. *Id.* The determination of whether there is an actual controversy between the parties turns on "the Article III mandate that the injury in fact be 'concrete,' and 'actual or imminent, not conjectural or hypothetical.' " *Id.* (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

First, the court notes the similarities between Mylan's position here and Teva's in *Teva*, where the Federal Circuit court held that Teva failed to demonstrate a reasonable apprehension of suit. *Id.* at 1334. The similarities include Mylan's "virtual conce[ssion] that [Merck] will not bring immediate suit for infringement of the [finasteride patents],"⁷ and the fact that "[Merck] need not sue [Mylan] immediately" because the FDA cannot approve Mylan's ANDA for generic finasteride before Ivax's 180-day exclusivity period expires. *See id.*

Moreover, the nature of Merck's litigation against Dr. Reddy's regarding two of its finasteride patents and against other companies regarding other patents is insufficient to establish that, under the instant circumstances, Mylan has a reasonable apprehension of suit. Merck's infringement suit against Dr. Reddy's involving the finasteride patents, although relevant, does not on its own convey a reasonable

⁷ Mylan points to Merck's suit against Dr. Reddy's two years after the filing of Dr. Reddy's ANDA for generic finasteride/PROPECIA® and speaks in terms of Merck's possible "future intentions."

apprehension of suit to Mylan. Although the *Arrowhead* court determined that reasonable apprehension existed where a patentee had previously filed suit involving the same patent against another company, it did so where there were additional factors that, taken together, satisfied the totality of circumstances test. 846 F.2d at 737. An infringement suit against another filer, even to protect the same patent, does not conclusively establish a reasonable apprehension of suit. *See Dr. Reddy's Labs., Ltd. v. Pfizer, Inc.*, No. Civ. A. 03-CV-726, 2003 WL 21638254, at *6 (D. N.J. Jul. 8, 2003) (Pfizer's suit against first ANDA filer and involving same patent did not establish reasonable apprehension of suit for subsequent ANDA filer).

Mylan points to nothing more than the bare fact that Merck filed suit against Dr. Reddy's for finasteride patents for a different brand name product (PROPECIA®). It suggests no other similarities between the Dr. Reddy's circumstances and its own and, in fact, fails to identify specifically which finasteride patents are at issue in that action (Mylan identifies them only as "other Merck-owned finasteride patents). In addition, Merck has not sued Ivax, the first filer here, or any other filer regarding the finasteride patents for PROSCAR®. Accordingly, the court finds that Merck's conduct with respect to Dr. Reddy's fails to establish a reasonable apprehension of suit for Mylan.

Merck's history of enforcing other patents against other companies, although relevant, also fails to establish a reasonable apprehension of suit for Mylan. A patentee's history of enforcing patents generally does not in and of itself provide any indication regarding the patentee's intentions regarding other patents. *See Mutual Pharm. Co. v. Pfizer Inc.*, 307 F. Supp. 2d 88, 93-94 (D.D.C. 2004); *Dr. Reddy's Labs*, 2003 WL 21638254, at *7. Moreover, [i]n cases where courts have

found prior litigation sufficiently threatening, either (1) the defendant referenced that litigation in some communication to the plaintiff, or (2) there was ongoing litigation between the parties over a series of closely related patents involving the same technology.” *Apotex, Inc. v. Pfizer Inc.*, 385 F. Supp. 2d 187, 194 (S.D.N.Y. 2005) (internal citations omitted). No such communication or ongoing litigation between the parties involving the same technology exist here. Accordingly, Merck’s prior history of litigation regarding its other patents fails to establish a reasonable apprehension of suit for Mylan.

3. Public Statements

Mylan also bases its reasonable apprehension argument on statements Merck published in its annual and quarterly reports. The statement that “[Merck] intends to vigorously defend its patents, which it believes are valid, against infringement by generic companies attempting to market products prior to the expiration dates of such patents,”⁸ on its own, fails to establish a reasonable apprehension of suit for Mylan. “[A] patent holder’s statement that it intends to enforce its patent does not [necessarily] create a reasonable apprehension of suit.” *Torpharm, Inc. v. Pfizer Inc.*, No. Civ. 03-990-SLR, 2004 WL 1465756, at *41 (D. Del. June 28, 2004), *vacated as moot*, 125 Fed. Appx. 987 (Fed. Cir. 2005)

⁸ The relevant language in its entirety reads “Generic pharmaceutical manufacturers have submitted ANDAs to the FDA seeking to market in the United States a generic form of *Fosomax*, *Prilosec* and *Propecia* prior to the expiration of the Company’s (and AstraZeneca’s in the case of *Prilosec*) patents concerning these products. The generic companies’ ANDAs generally include allegations of non-infringement, invalidity and unenforceability of the patents. Generic manufacturers have received FDA approval to market a generic form of *Prilosec*. The Company has filed patent infringement suits in federal court against companies filing ANDAs for generic alendronate and finasteride and AstraZeneca and the Company have filed suits in federal court against companies filing ANDAs for generic omeprazole. Similar patent challenges exist in certain foreign jurisdictions. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by generic companies attempting to market products prior to the expiration dates of such patents.”

(determined to be moot when Pfizer entered into covenant not to sue Torpharm for infringement) (citing *Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha*, 57 F.3d 1051, 1054 (Fed. Cir. 1995)).

Merck's statement is "of a general nature, directed to [an] overall strategy of enforcing [Merck's] patent rights against generic competition" and is "not specifically directed against [Mylan], nor is there any evidence suggesting that it was made with [Mylan] in mind." *Id.* (declining to find that a statement that Pfizer would "continue aggressively to defend challenges to [its] intellectual property" in a press release regarding an infringement suit against the first ANDA filer for the same patent implicated by Torpharm's ANDA). Moreover, courts have found patentee communications to be threatening in contexts where they 1) specifically link the prospect of litigation to questions concerning an ANDA filer's ability to make a generic drug properly without the patents or 2) otherwise link a policy of enforcement or likelihood of litigation to a specific generic company in letters or other communications, thus implicitly conveying a threat of litigation. *See, e.g., Dr. Reddy's Labs., Ltd. v. aaiPharma Inc.*, No. 01 Civ. 10102(LAP), 2002 WL 31059289, at *3-4 (S.D.N.Y. Sept. 13, 2002) (patentee stated in two *Wall Street Journal* articles that it would be "unlikely" or "difficult for" generic companies to make Prilosec properly without using patents and that if generic companies "refused to pay" patentee for licenses, a "threat of a lawsuit" existed); *DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397, 1401 (Fed. Cir. 1995) ("Bristol-Myers' stated policy, *together with letters* sent by Bristol-Myers to DuPont Merck/Endo and Mylan relating to the '776 patent, create a reasonable apprehension on the part of DuPont Merck/Endo and Mylan.") (emphasis added); *Kos Pharms,*

Inc. v. Barr Labs., Inc., 242 F. Supp. 2d 311, 316 (S.D.N.Y. 2003) (Kos' statement that it would "aggressively enforce" its patents was made in a press release discussing the underlying litigation between the parties).

No such communications have occurred between Merck and Mylan. The only specific communications referenced here are Merck's June 9, 2005 letter stating that it would not sue Mylan for infringement within the forty-five-day period and its October 5, 2005 letter declining Mylan's proposed covenant and stipulation of non-infringement. The June 9 letter addressing Merck's intentions for the forty-five-day period makes no other representations about Merck's intentions and contains no reference to or statement of a policy of patent enforcement on the part of Merck.

The October 5 letter declining to enter into a covenant or stipulations similarly contains no representations about Merck's intentions regarding a law suit. The letter simply conveys Merck's beliefs that it is not obligated to enter into a covenant and that the instant action is inappropriate. Thus, Mylan fails to identify any communications from Merck that would recast its stated general enforcement strategy in a way that would establish a reasonable apprehension of suit for Mylan.

4. Refusal to Covenant

Mylan also argues that Merck's refusal to grant Mylan a covenant not to sue supports its contention that a reasonable apprehension of suit exists. Mylan correctly notes that this is a relevant factor; however, it is not dispositive. *Teva*, 395 F.3d at 1333 (citing *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed. Cir. 1993)). Moreover, Merck is under no statutory obligation to provide a covenant

or otherwise assure Mylan that it will not sue for infringement. *See Teva Pharms. USA, Inc. v. Pfizer Inc.*, No. Civ. A. 03CV10167RGS, WL 2003 WL 22888848, at *4 (D. Mass. Dec. 8, 2003), *aff'd Teva*, 395 F.3d 1324. Mylan argues that Merck's statement that it would not sue within the forty-five-day period following notice of Mylan's ANDA, without a covenant not to sue, includes the unspoken inference of "yet." This argument is simply too speculative to establish a reasonable apprehension of suit for Mylan under the instant circumstances.

5. Statutory Civil Suit Provision

Finally, Mylan argues that the Medicare Amendments, through the declaratory judgment provision, provide a means of satisfying Article III's requirements without satisfying the reasonable apprehension of suit prong of the two-part test. The Federal Circuit squarely addressed this issue in *Teva* and

conclude[d] that the plain language of the statute, as well as the legislative history, support the conclusion that Congress did not intend for the Medicare Amendments to cause courts to alter the requirement of the two-part test that a declaratory judgment plaintiff must demonstrate a "reasonable apprehension" of suit to establish Article III jurisdiction. [The] traditional two-part test remains good law

395 F.3d at 1337. Accordingly, the court will rely upon the traditional two-part test in making its finding that none of the above factors relied upon by Mylan, taken alone or taken together, establish a reasonable apprehension of suit. Therefore, the court lacks subject matter jurisdiction to consider Mylan's request for declaratory judgment.

IV. Conclusion

For the foregoing reasons, the court grants Merck's Motion to Dismiss for lack of subject matter jurisdiction. Accordingly, the court denies Merck's Contingent Motion to Transfer Under 28 U.S.C. § 1404(a) as moot.

s/Sylvia H. Rambo

SYLVIA H. RAMBO

United States District Judge

Dated: October 28, 2005.

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA		
MYLAN PHARMACEUTICALS INC.,	:	Civil No. 1:05-CV-1416
Plaintiff,	:	JUDGE SYLVIA H. RAMBO
v.	:	Jury Trial Demanded
MERCK & CO., INC.,	:	
Defendant.	:	